CAPSTONE® Spinal System
510(k) Summary

November 2013

I. **Company:**

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: Greg Maschek
Regulatory Affairs Specialist

II. **Proprietary Trade Name:** CAPSTONE® Spinal System

III. **Common or Usual Name:** Intervertebral Body Fusion Device

IV. **Classification Name:** Intervertebral Fusion Device With Bone Graft, Lumbar (21 CFR 888.3080)

V. **Product Code:** MAX

VI. **Product Description:**

The purpose of this 510(k) submission is to add additional CAPSTONE® Spinal System implants with 3°, 6°, and 9° options for angles of lordosis. The subject devices are being included to this system in order to provide the surgeon with additional options to accommodate varying patient anatomies. Additionally, subject trial instruments corresponding to the angles of lordosis of the subject implants are included in this submission.

The CAPSTONE® Spinal System consists of PEEK cages, titanium alloy cages and titanium cage of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft. The CAPSTONE® Spinal System includes various instruments, including trials, used to assist in placement of the implants.

VII. Indications for Use:

The CAPSTONE® Spinal System is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Additionally, the CAPSTONE® Spinal System is indicated in the setting of spinal deformity as a supplement to pedicle screw fixation in patients diagnosed with degenerative scoliosis.

These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

VIII. Identification of Legally Marketed Predicate Devices Used to Claim Substantial Equivalence:

The CAPSTONE® Spinal System design features including options for heights, lengths, widths, and lordosis range, the indications for use, fundamental scientific technology, and sterilization are not new and exist in other legally marketed devices. These predicates include CAPSTONE® Spinal System (K073291, SE 4/24/2008; K123027, SE 07/25/2013; K121760, SE 08/29/2012) and CAPSTONE CONTROL™ Spinal System (K120368, SE 04/09/2012).

IX. Summary of the Technological Characteristics:

The purpose of this 510(k) submission is to include additional angles of lordosis for the CAPSTONE® Spinal System implants and corresponding trials. The subject and predicate CAPSTONE® Spinal System implant and trials are identical in terms of indications for use, intended use, performance specifications and technological characteristics. The key differences between the subject and predicate devices are the additional lordosis options for the CAPSTONE® Spinal System implants, and the addition of corresponding lordosis trials.

X. Discussion of Non-Clinical Testing:

A risk analysis of the device modifications was completed in accordance with Medtronic design control procedures. The risk analysis, which included an engineering rationale, demonstrated that the subject CAPSTONE® Spinal System does not introduce new issues of safety or effectiveness.

XI. Discussion of Clinical Testing:

No clinical testing was performed.

XII. Conclusions Drawn from the Non-Clinical Tests:

A risk analysis was completed for the modifications to the subject devices. Based on the results and additional supporting documentation provided in this submission, the subject devices demonstrated substantial equivalence to the previously listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2013

Medtronic Sofamor Danek USA, Incorporated
Mr. Gregory K. Maschek
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K133650
Trade/Device Name: CAPSTONE® Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: November 26, 2013
Received: November 27, 2013

Dear Mr. Maschek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133650

Device Name
CAPSTONE® Spinal System

Indications for Use *(Describe)*
The CAPSTONE® Spinal System is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of nonoperative treatment.

Additionally, the CAPSTONE® Spinal System is indicated to assist in the setting of spinal deformity as a supplement to pedicle screw fixation in patients diagnosed with degenerative scoliosis.

These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD
Division of Orthopedic Devices